

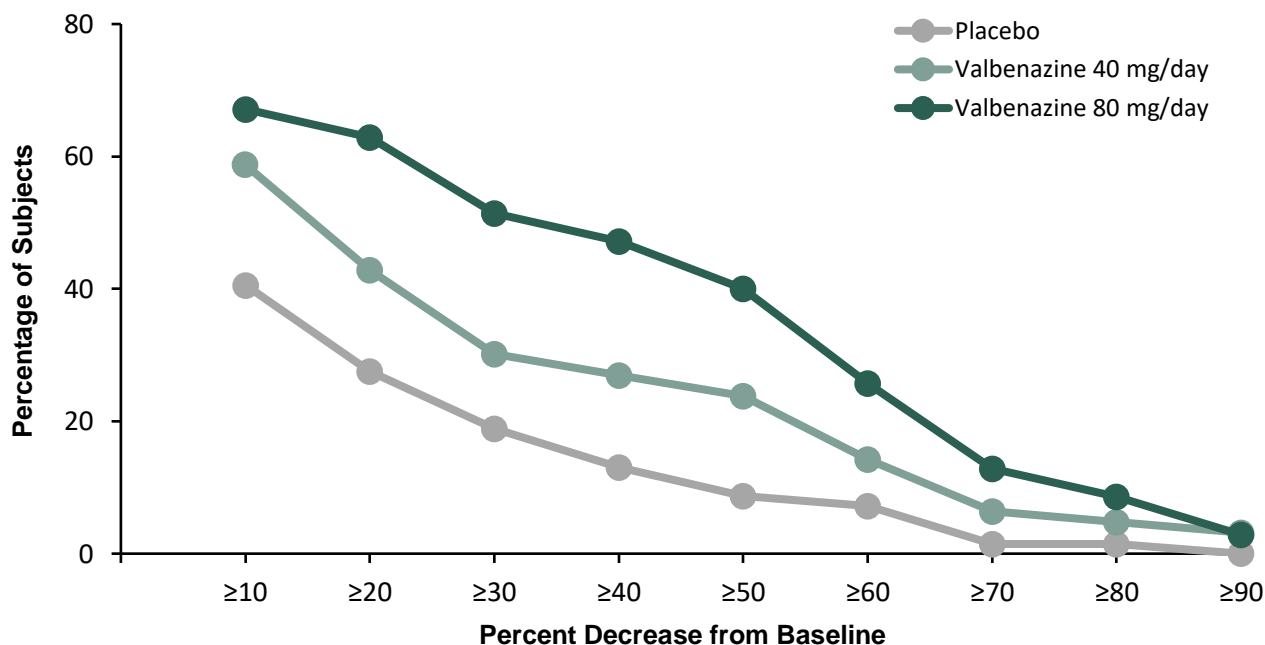
Participants with Tardive Dyskinesia Not Responding (“Non-Responders”) to INGREZZA® (valbenazine) Capsules and INGREZZA® SPRINKLE (valbenazine) Capsules

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding information on participants with tardive dyskinesia (TD) defined as not responding to INGREZZA or INGREZZA SPRINKLE (“non-responders”).

INGREZZA and INGREZZA SPRINKLE are vesicular monoamine transporter 2 (VMAT2) inhibitors indicated for the treatment of adults with tardive dyskinesia.¹

There is no formal definition of response in tardive dyskinesia as the clinical presentation of the condition is variable, with severity and impact differing for each patient. In lieu of a “non-responder analysis,” **Figure 1** (below) demonstrates the cumulative percentages of participants, by study arm, who achieved certain thresholds of TD reduction in the double-blind, placebo-controlled portion of the pivotal KINECT® 3 study as measured by the Abnormal Involuntary Movement Scale (AIMS) total score.²

Figure 1: AIMS Cumulative Response at Week 6 (ITT Population)



AIMS, Abnormal Involuntary Movement Scale; ITT, intent-to-treat.

The safety of valbenazine was evaluated in 3 placebo-controlled studies, each 6 weeks in duration including a total of 445 participants. During the three studies, the adverse reactions reported at >2% and >placebo were somnolence (somnolence, fatigue, sedation) (10.9% vs. 4.2%), anticholinergic effects (dry mouth, constipation, disturbance in attention, vision blurred, urinary retention) (5.4% vs. 4.9%), balance disorders/fall (4.1% vs. 2.2%), headache (3.4% vs. 2.7%), akathisia (2.7% vs. 0.5%), vomiting (2.6% vs. 0.6%), nausea (2.3% vs. 2.1%) and arthralgia (2.3% vs. 0.5%) for the valbenazine and placebo groups, respectively.¹

This letter and the enclosed material are provided in response to your unsolicited medical information inquiry. Please feel free to contact Neurocrine Medical Information at (877) 641-3461 or medinfo@neurocrine.com if you would like to request additional information.

References:

1. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
2. Hauser RA, et.al. KINECT 3: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Valbenazine for Tardive Dyskinesia. American Journal of Psychiatry. 2017; 174(5):476-84. doi:10.1176/appi.ajp.2017.16091037 (<https://www.ncbi.nlm.nih.gov/pubmed/28320223>).

Enclosures:

- A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
- B. INGREZZA [Important Safety Information]. San Diego, CA: Neurocrine Biosciences, Inc.